PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 17843 PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00773	International filing date *(day/month/year)* 11.11.2003	Priority date *(day/month/year)* 11.11.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/195		
Applicant PHARMALETT A/S		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.06.2004	17.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Beeck, M Telephone No. +49 89 2399-8473

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00773

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-24 as originally filed

Claims, Numbers

1-25 filed with telefax on 03.02.2005

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-25
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-25
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	

2. Citations and explanations

see separate sheet

D1: US-A-6 066 341 (WILSON COLLEEN G) 23 May 2000 (2000-05-23)
D2: WO 85/01441 A (GJERLOEV MOGENS) 11 April 1985 (1985-04-11)

SECTION V:

1) The subject-matter of the claims is novel.

2) Closest prior art document is D1 from which the subject-matter of the claims differs in that the contents of Isphagula Husk is lower, namely between 5 and 30 weight percent.

Hence, the problem to be solved by the invention was to reduce side effects of Isphagula Husk.

The solution to the problem was to diminish the contents of Isphagula Husk.

The person skilled in the art would then turn to document D2 which describes compositions for the same use also comprising Isphagula Husk, but no amino acid, in a low amount of about 40 % (see the examples 1 and 2).

Since in D1 and D2 the use is the same the person skilled in the art could combine the teachings of D1 and D2, but the subject-matter of new claims 1 to 4 still differs from the teaching of the combination of D1 and D2 in that the contents of Isphagula is still at least 10 % lower.

Therefore in view of these differences the subject-matter of the claims is not obvious for the person skilled in the art, so that the subject-matter of the claims involves an inventive step.

PATENT CLAIMS

1. A preparation comprising:

5-50% by weight of Isphagula Husk, and

1-20% by weight of at least one amino acid, and

20-80% by weight of at least one carbohydrate and electrolytes for use as a therapeutical agent.

2. A preparation comprising:

5-50% by weight of Isphagula Husk, and

1-20% by weight of at least one amino acid, and

20-80% by weight of at least one carbohydrate and electrolytes said Isphagula Husk, at least one amino acid and at least one carbohydrate and electrolytes as a combined preparation for simultaneous or sequential use in treating a state of disorder of the intestinal system of monogastric animals, including human beings.

3. A preparation for treating a state of disorder of the intestinal system of monogastric animals, including human beings, said preparation comprising:

5-50% by weight of Isphagula Husk, and

1-20% by weight of at least one amino acid, and

20-80% by weight of at least one carbohydrate and electrolytes.

4. A preparation for restoring the epithelium layer of the intestines of mammals, including human beings, said preparation comprising:

5-50% by weight of an agent comprising Isphagula Husk, and

1-20% by weight of at least one amino acid,

20-80% by weight of at least one carbohydrate and electrolytes.

5. A preparation according to any one of claims 1 to 4, wherein the amount of Isphagula Husk is in the interval of 10-40% by weight, preferably 15-35% by weight, more preferably 25-30% by weight.

6. A preparation according to any one of claims 1 to 4, wherein the amount of the at least one amino acid is in the interval of 1-12% by weight, preferably 2-9 % by weight, more preferably 3-7 % by weight.

7. A preparation according to any one of claims 1 to 4, wherein the amount of carbohydrate is in the interval of 25-50% by weight, preferably 30-45% by weight, more preferably 35-40% by weight.

8. A preparation according to any one of claims 1 to 4, wherein the amount of electrolyte is in the interval of 8-40% by weight, preferably 12-30% by weight, more preferably 15-25% by weight.

9. A preparation according to any one of the preceding claims, wherein the at least one amino acid is comprised in the soluble components of lactic yeast.

10. A preparation according to any one of the preceding claims, comprising at least one amino acid selected from the group consisting of all known amino acids, preferably at least one amino acid selected from the group consisting of glutamine, arginine, lysine, histidine, phenylalanine, tyrosine, leucine, isoleucine, methionine, valine, alanine, glycine, proline, glutamic acid, serine, threonine, aspartic acid, tryptophan, cystine, more preferably at least one amino acid selected from the group consisting of glutamine, arginine, alanine and glycine.

11. A preparation according to any one of the preceding claims, wherein the amount of glutamine is in the interval of up to 10% by weight, preferably up

to 5% by weight, more preferably 0.1-4% by weight, even more preferably 0.2-3% by weight.

12. A preparation according to any one of the preceding claims, wherein the amount of arginine is in the interval of up to 5% by weight, preferably up to 3% by weight, more preferably 0.1-2% by weight, even more preferably 0.1-0.5% by weight.

13. A preparation according to any one of the preceding claims, wherein at least one of the salts comprised by the electrolytes and is at least one of the salts which will replace at least one of the salts lost by diarrhoea.

14. A preparation according to any one of the preceding claims, wherein said at least one carbohydrate is glucose.

15. A preparation according to any one of the preceding claims, wherein the electrolytes are a mixture of at least two of the substances selected from the group consisting of magnesium oxide, magnesium carbonate hydroxide, magnesium hydroxide, magnesium silicate, calcium silicate, calcium carbonate, sodium chloride, potassium chloride, sodium hydrogen carbonate, potassium hydrogen carbonate, aluminium phosphate, aluminium hydroxide, citric acid, sodium citrate, trisodium citrate dihydrate and potassium citrate.

16. A preparation according to any one of the preceding claims, wherein the electrolytes are a mixture of at least two of the substances selected from the group consisting of magnesium hydroxide, sodium chloride, potassium chloride, sodium hydrogen carbonate, citric acid, trisodium citrate dihydrate and sodium citrate.

17. A preparation according to any one of the preceding claims, further comprising at least one filler, at least one taste corrigent, at least one colouring agent.

18. A preparation according to any one of the preceding claims, further comprising a filler.

19. A preparation according to claim 18, wherein the filler is a fibrous bran material.

20. A preparation according to claim 18, wherein the filler is wheat flour.

21. A preparation according to any one of the preceding claims, further comprising a pharmaceutically acceptable colouring agent.

22. A preparation according to any one of the preceding claims, wherein the colouring agent is FD&C RED #40.

23. A preparation according to any one of the preceding claims, further comprising alfa-tocoferol (natural vitamin E).

24. A preparation according to any one of the preceding claims, wherein said preparation consists of 27.16% Isphagula Husk,10.66% of lactic yeast mixture including glutamine, 19.75% electrolytes which are made up of 3.30% potassium chloride, 7.08% sodium hydrogen carbonate, 4.85% sodium chloride, 3.45% trisodium citrate dihydrate, 1.07% magnesium hydroxide; 38.10% dextrose monohydrate, 0.87% nicotinamide, 0.30% flavouring agent, 0.20% silicium dioxide, 2.43% wheat flour, 0.03% feed colouring agent, 0.50% alfa-tocoferol (natural vitamin E), where the percent by weight is calculated on the basis of the finished preparation.

25. Use of a preparation according to any one of the preceding claims for the manufacture of a medicament for treating diarrhoea.